DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

~~DEPARTMENT OF HEALTH AND HUMAN SERVICES~~

Food and Drug Administration
College Park, MD 20740

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MAY 11 2004

Mr. Colin Cooper
President
Herbal Health, Inc.
1535 Meadowvale Road
Santa Ynez, California 93460

Dear Mr. Cooper:

This is in response to your letter to the Food and Drug Administration (FDA) dated April 29, 2004 regarding the regulatory requirements for dietary supplements. Specifically, you asked FDA to review certain labels and labeling for a dietary containing an ingredient called Aloe Ferox Bitter Crystals.

Dietary supplements are regulated under the provisions of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Dietary Supplement Health and Education Act of 1994. Regulations implementing certain requirements of the Act are published in Title 21 of the Code of Federal Regulations (21 CFR). Generally, there is no requirement for premarket review or approval of dietary supplements. It is the manufacturer's responsibility to ensure that its products are in compliance with applicable requirements of the Act and regulations promulgated under the Act. FDA does not approve dietary supplements or their ingredients. In that we have not reviewed any information on the safety of the ingredient you inquired about and do not otherwise have information that would enable us to determine whether it or a product that may contain it complies with the requirements of the Act, we are unable to provide you with any opinion as to whether it may lawfully be marketed as a dietary supplement. Moreover, while we have, in the past offered comments informally as to whether food labels comply with the laws we administer, due to volume of requests for label reviews in conjunction with the limited staff available to provide general label review assistance, we are not able to respond to requests for general label reviews. Consequently, we have no comments on the compliance of your labels or promotional material with the requirements of the Act or the agency's regulations. We have enclosed an information sheet the summarizes the basic regulatory requirements that pertains to dietary supplements.

We would, however, like to comment on one specific aspect of your product. If the ingredient in your product was not marketed as a dietary supplement or food in the United States before October 15, 1994, then it is a new dietary ingredient for which a premarket notification may be required. This briefly describes the statutory requirements that apply to the use of a substance in dietary supplements that may be a new dietary ingredient under section 413 of the Act (21 U.S.C. 350b).

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21 U.S.C. 350b provides that a dietary supplement that contains a new dietary ingredient shall be deemed adulterated under 21 U.S.C. 342(f) unless it meets one of two requirements:

> (1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or
>
> (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

If a firm is not aware of any information demonstrating that the dietary ingredient of interest was lawfully marketed in the United States before October 15, 1994, it may be a "new dietary ingredient" under 21 U.S.C. 350b(c) and it would be subject to the notification requirement in 21 U.S.C. 350b(a)(2) and 21 CFR 190.6. In order to market a dietary supplement containing such a new dietary ingredient, a firm would have to submit to FDA for its review the information that is the basis on which it has concluded that a dietary supplement containing the a new dietary ingredient will be reasonably be expected to be safe. Introduction into interstate commerce of a dietary supplement containing a new dietary ingredient for which the required submission has not been made is prohibited under 21 U.S.C. 331(v). Moreover, a dietary supplement containing such an ingredient would, therefore, be deemed adulterated and subject to regulatory action pursuant to 21 U.S.C. 342(f)(1)(B).

Under 21 U.S.C. 350b(a)(2) and 21 CFR 190.6, a firm must submit to FDA the information that is the basis on which it has concluded that a dietary supplement containing the new dietary ingredient will be reasonably be expected to be safe. The firm is responsible for determining what information provides the basis for its decision; at this time, FDA has not published guidance defining the specific information that the submission must contain. More information on new dietary ingredients can be found on our website at http://www.cfsan.fda.gov/~dms/ds-ingrd.html.

Please contact us if we may be of further assistance.

Sincerely yours,

Robert J. Moore
Team Leader, Compliance and Enforcement
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

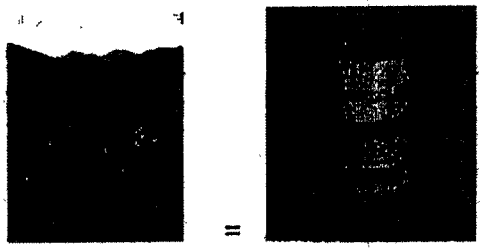
[redacted]

Aloe Ferox

Bitter crystal capsules

Consumer information

Each capsule contains pure Aloe ferox crystal powder.
100% natural **organic** product
Dietary Supplement



Suggested use: Take one capsule, once a day in morning
before meal, with ample water.

Aloe Ferox is a unique herb that has been used by healers in Africa for hundreds of years. It is organic and found in abundance in the wilds of South Africa. Only the leaves are harvested - the plant itself is not destroyed. It should not be confused with Aloe Vera from South America.

Aloe ferox is a fleshy plant with spikes and red flowers. Its importance in the life of the Khoi and San peoples of Southern Africa can still be seen in their paintings on the walls of their ancient cave dwellings.

The bitter crystal of this Aloe contains aloin and other anthraquirones. The indigenous people at the Cape produced aloe bitter crystals for the relief of rheumatic conditions and as a "blood cleaner". Aloe ferox crystals have been thoroughly researched by scientists and reported in many scientific publications, including the main Pharmacopoeias of the world.

The aloe ferox plant derives it's name from the ferocious thorns (ferox Latin) which cover the leathery surface of the leaves. These thorns protect the all-important life sustaining fleshy core of the leaf from Africa's numerous herbivores.

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*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure or prevent any disease.

Store in a cool dry place out of reach of children

Do not use if you are pregnant, have or develop diarrhea, loose stools, or abdominal pain, because Aloe ferox may worsen these conditions and be harmful to your health

Distributed by:
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Colin Cooper
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1535 Meadowvale Rd
SantaYnez CA 93460
Fax 805-686 2876
April 29th, 2004

Attention Gerald M. Rachanow
Division of Over the Counter Drug Products
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857

Dear Mr Rachanow

As I discussed with you on the telephone today, we would like to produce and supply aloe ferox bitter crystal powder in a micro #5 capsule, as a herbal supplement.

Aloe ferox product has been used for many, many years, and in has been known to help for general health.

I am enclosing herewith 3 of the proposed labels that we have made, and an informational leaflet that we would enclose with the products, for your evaluation.

I look forward to receiving your comments on whether we will be able to market this product.

Your sincerely

Colin Cooper
President
Herbal Health Inc